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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,796	04/02/2008	H. Lee Sweeney	PENN0870US.NP	8993

26259 7590 10/29/2010

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
10/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,796	SWEENEY ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election **with traverse of muscular dystrophy** in the reply filed on 4/9/2010 is acknowledged. The traversal is on the ground(s) that there are only 4 species and that there is no burden on the examiner to search all of the species. This is not found persuasive because each disease/disorder is completely different from one another. Applicant is reminded that if the examiner does not find the elected species, the examiner will search another one of the species. Art was found on muscular dystrophy thus the species was found.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of treating or **inhibiting progression of skeletal muscle atrophy in a subject** comprising administering a Bowman-Birk Inhibitor concentrate or **a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk Inhibitor**.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to " **a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk Inhibitor"**. The specification gives no evidence as to what "**a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk Inhibitor"** means or what it is. All the specification states on page 13, is

by "synthetic" it is meant to include both recombinant and chemical means for compound. That tells one of ordinary skill in the art practically nothing. Thus, the claims lack written description. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed "**a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk Inhibitor"**.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only Bowman-Birk inhibitor concentrate, but not the full breadth of the claims (**a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk Inhibitor"**) meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

4. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skeletal muscle atrophy in a subject does not enable **inhibiting progression of skeletal muscle atrophy in a subject**

comprising administering a Bowman-Birk Inhibitor concentrate or **a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk**.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

With respect to the Wands factors above (particular as they pertain to the quantity of experimentation necessary as well as the state of the prior art within the medical field), Applicants have reasonably demonstrated/disclosed that the claimed composition is useful as a therapeutic agent for treating skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate. However, the claims also encompass using the claimed extract composition to **inhibit progression of skeletal muscle atrophy in a subject** comprising administering a Bowman-Birk Inhibitor concentrate or **a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk**.

Inhibiting progression of skeletal muscle atrophy in a subject is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "inhibit" is the same as "prevent" since inhibit means to stop from occurring which is prevention. "Inhibit" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "delaying" (or --treating--), especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented/inhibited with current therapies.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to use the instantly claimed composition in a manner so as to provide the functional effect instantly claimed with respect to "Inhibiting progression of skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate via administering the recited composition to a patient in need thereof ".

It is strongly suggested that the phrase **" inhibiting progression of skeletal muscle atrophy in a subject"** be omitted from the claims to overcome the USC 112, first paragraph rejection immediately above in response to this Office action.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

> The term, "**a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk** is vague and indefinite. What does "**a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk**" mean anyway ? There are no metes and bounds to this term. All the specification states on page 13 is by "synthetic" it is meant to include both recombinant and chemical means for compound. How does this make the phrase understandable to one having ordinary skill in the art ?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Morris et al. (supplied by applicants).

Morris teaches that Bowman Birk Inhibitor (BBI) is used to attenuate (reduce) the skeletal muscle mass loss associated with disuse atrophy in mice, see abstract. Thus, if the skeletal muscle mass loss is reduced then progression of a skeletal muscle atrophy is treated, symptoms of a subject suffering from a degenerative skeletal muscle disorder are alleviated (muscle mass loss) , skeletal muscle function in a subject is improved, and skeletal muscle degeneration is treated (muscle mass).

As is stated on page 1 of the instant specification, skeletal muscle atrophy, the loss of muscle mass, is associated with removal of load-induced signaling either during disuse or under microgravity conditions. This atrophy is mediated by slowing/inhibition of growth signaling pathways and an increase in pathways associated with protein degradation (Goldberg, A.L. J Biol Chem 1969 244: 3223-3229; Jaspers, S.R. and Tischler, M.E. J Appl Physiol 1984 57: 1472-1479;

Loughna et al. J Appl Physiol 1986 61: 173-179). This rapid loss of muscle mass and strength, especially in an aging population, represents a significant health problem.

Thus, Morris teaches the claimed invention since when the disuse atrophy is reduced the muscle's mass will be increased since the decrease in muscle mass is reduced. Note oral use in a dietary supplement, see abstract.

9. Claims 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al. (US 5961980).

Kennedy teaches that Bowman Birk Inhibitor (BBI) is used to treat abnormal conditions occurring in the pelvic region related to smooth muscle contractions, see col. 1, lines 1-25. Oral use is taught at col. 7, lines 45-end. Thus, when one orally consumes the BBI it will inherently improve skeletal muscle function since the same BBI as claimed is administered, thus it will inherently perform the same method since the same composition is being administered as is claimed. Note dietary supplement, col. 7, lines 50-end.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (supplied by applicants) in view of Lynch.

Morris teaches that Bowman Birk Inhibitor (BBI) is used to attenuate (reduce) the skeletal muscle mass loss associated with disuse atrophy in mice, see abstract. Thus, if the skeletal muscle mass loss is reduced then progression of a skeletal muscle atrophy is treated, symptoms of a subject suffering from a degenerative skeletal muscle disorder are alleviated (muscle mass loss) , skeletal muscle function in a subject is improved, and skeletal muscle degeneration is treated (muscle mass).

As is stated on page 1 of the instant specification, skeletal muscle atrophy, the loss of muscle mass, is associated with removal of load-induced signaling either during disuse or under microgravity conditions. This atrophy is mediated by slowing/inhibition of growth signaling pathways and an increase in pathways associated with protein degradation (Goldberg, A.L. J Biol Chem 1969 244: 3223-3229; Jaspers, S.R. and Tischler, M.E. J Appl Physiol 1984 57: 1472-1479; Loughna et al. J Appl Physiol 1986 61: 173-179). This rapid loss of muscle mass and strength, especially in an aging population, represents a significant health problem.

Thus, Morris teaches the claimed invention since when the disuse atrophy is reduced the muscles mass will be increased since the decrease in muscle mass is reduced. Note oral use in a dietary supplement, see abstract.

Morris does not teach that muscular dystrophy is treated by BBI.

Lynch teaches that muscular dystrophies are generally characterized by progressive skeletal muscle wasting and weakness, see abstract of Lynch.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use BBI to treat muscular dystrophy because

Morris teaches that disuse atrophy reduces (attenuates) skeletal muscles mass which is clearly critical and beneficial in a patient having muscular dystrophy (MD) since muscular dystrophies are generally characterized by progressive skeletal muscle wasting and weakness, see Lynch, abstract. Thus, one having MD will have muscle weakness and can then be therapeutically treated with BBI with the expectation of reducing muscle mass loss and thus increasing muscle strength which is what someone having MD needs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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